

REMARKS

The present Amendment is in response to the Non-Final Office Action mailed December 4, 2008, in the above-identified patent application. Enclosed herewith is a one-month extension fee for resetting the deadline for responding to the Non-Final Office Action from March 4, 2009, to an including April 4, 2009. Applicants note that the present Amendment is timely filed within the one-month extension period because the United States Patent and Trademark Office was closed on April 4, 2009, which was a Saturday.

Applicants submit herewith an Applicant Initiated Interview Request Form.

In the present Amendment, Applicants have amended claims 1, 2, 33, 38, and 46, and have added new claims 47 and 48 that depend from independent claim 1. The above-noted changes are fully supported by the originally filed specification and add no new matter.

The present application now has four independent claims and 29 total claims. No additional claim fees are due because Applicants previously paid for four independent claims and 31 total claims.

In one embodiment, the present application discloses an intravaginal occlusion device used for occluding blood flow in a female patient's uterine arteries when the patient has an asymmetrical uterine artery anatomy. In one embodiment, the occlusion device has first and second pressure applying occluding elements with each pressure applying occluding element having independent distal movement and independent pivoting movement for engaging the asymmetrical uterine anatomy. As will be set forth in more detail below, the prior art references cited by the Examiner do not teach the combination of independent distal movement and independent pivoting movement for a pair of pressure applying occluding elements.

In the Office Action, the Examiner rejected claims 1-6, 12, 15-18, 21 and 22 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 7,354,444 to Burbank et al. On page 3 of the Office Action, the Examiner asserts that Burbank discloses "a first mechanism/extending actuator (41) to distally extend at least part of the first pressure applying occluding element from a first position closer to the first operative proximal shaft section (as in fig. 1) to a second position further away from the first operative proximal shaft section (as in fig. 8)." In response, Applicants note that Burbank '444 teaches a release lever 36 (FIG. 1) coupled with release lines 41 that extend between the release lever and anchoring elements 32. Referring to FIG. 2A, the anchoring elements 32 have recesses 44 adapted to receive dowels 46 on paddles 14. Referring to FIGS. 2A and 2C, as the release lever 36 is moved to a locked position, the release

lines 41 move distally, which, in turn, move locking pins 38 distally. As the locking pins 38 move distally, teeth 39 on collets 33 move outwardly to “engage a paddle 14 when in an expanded configuration, effective to hold paddles 14 securely on or adjacent distal arms 48 of handles 20.” Col 6, lines 1-4. As such, Applicants respectfully assert that the release lever 36 and the release lines 41 are used for locking and releasing the paddles 14 from a distal end of the instrument, and are not used to move the paddles distally from a proximal end of the device as asserted by the Examiner.

In view of the above, Applicants respectfully assert that claim 1 is unanticipated by Burbank '444 because the cited reference does not teach an intravaginal device including “a first distal shaft section with a first pressure applying occluding element secured to the first distal shaft section, and a first mechanism to distally extend at least part of the first pressure applying occluding element from a first position closer to the first operative proximal shaft section to a second position further away from the first operative proximal shaft section.”

Claim 2 is unanticipated by Burbank '444 because the reference does not teach an intravaginal device including a second occluding member whereby “the second occluding member has a second mechanism to distally extend at least part of the second pressure applying occluding element from a first position closer to the second operative proximal shaft section to a second position further away from the second operative proximal shaft section, wherein the first and second mechanisms to distally extend operate independently of one another so that the first and second pressure applying occluding elements are distally extendable independently of one another.” Claim 2 is also unanticipated, *inter alia*, by virtue of its dependence from independent claim 1, which is unanticipated for the reasons set forth above.

Claims 3-6, 12, and 15-18, are unanticipated, *inter alia*, by virtue of their dependence from independent claim 1, which is unanticipated for the reasons set forth above.

Claim 21 is unanticipated because Burbank '444 does not teach an intravaginal device “wherein the first pressure applying occluding element is distally extendable from the first distal shaft section a distance of up to one inch.” Claim 22 is unanticipated because Burbank '444 does not teach an intravaginal device “wherein the first pressure applying occluding element is distally extendable about 0.25 to about 0.8 inch from the first distal shaft section.” As noted above, Burbank's paddles 14 are not distally extendable. The release lever 36 (FIG. 1) is operative for securing and releasing the paddles from the distal end of the instrument. Claims 21 and 22 are also unanticipated, *inter alia*, by virtue of their dependence from independent

claim 1, which is unanticipated for the reasons set forth above.

The Examiner rejected claims 1-6 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,562,680 to Hasson. Referring to FIGS. 6 and 7 thereof, Hasson '680 teaches an instrument 10 having an outer casing 78 and claws 82 that are extendable from an internal opening 98 at a distal end 81 of the outer casing 78. The claws 82 are used to hold a moisture absorbent material 40 at the distal end 81 of the outer casing 78. Referring to FIG. 7, a spring mounted block 86 is movable toward a second block 88 for extending the claws 82 from the distal end 81 of the outer casing 78 so that the claws 82 may grab moisture absorbent material 40. The claws 82 are then fully retracted inside the internal opening 98 at the distal end 81 of the outer casing 78 for holding the moisture absorbent material 40 at the distal end 81 of the casing 78. Col. 6, lines 19-27.

In response to the rejection under Hasson '680, Applicants respectfully assert that the Examiner has not established a *prima facie* case of anticipation because the cited reference does not teach or disclose the claimed invention, nor does it enable one skilled in the art to practice the claimed invention. Claim 1 of the present application requires an "intravaginal device for occluding a female patient's uterine arteries" including "a first occluding member" with "a first pressure applying occluding element" and "a first mechanism to distally extend at least part of the first pressure applying occluding element." Claim 1 also requires "a second occluding member" with "a second pressure applying occluding element." Hasson '680 does not teach that the claws 82 are used for occluding uterine arteries, nor does the reference provide an enabling disclosure regarding how one skilled in the art could use the claws 82 to occlude uterine arteries. For these reasons, the Examiner has not established a *prima facie* case of anticipation under Hasson '680.

Claim 2 is also unanticipated because the Examiner has not established a *prima facie* case of anticipation, namely because Hasson '680 does not teach or disclose the claimed invention, nor does it enable one skilled in the art to practice the claimed invention. Specifically, Hasson '680 does not teach "a second mechanism to distally extend at least part of the second pressure applying occluding element." Claims 2-6 are unanticipated, *inter alia*, by virtue of their dependence from claim 1, which is unanticipated for the reasons set forth above.

The Examiner rejected claims 32-34, 36-41, and 43-46 under 35 U.S.C. § 103(a) as being unpatentable over Burbank in view of U.S. Patent No. 6,716,218 to Holmes and U.S. Patent No. 4,944,741 to Hasson. The Examiner cited Holmes as teaching an instrument having rotatable tips 40 (FIG. 1). The Examiner cited Hasson '741 as teaching "a rotating actuator for

rotating the pressure applying surface.” Applicants note, however, that Hasson ‘741 teaches using a single actuator 72 for simultaneously pivoting arms 28, 30. Specifically, Hasson ‘741 teaches that “[f]orward movement of the core 72 relative to the sleeve 22 effects forward shifting of the rod 46 and resultingly pivoting movement of the arm 28 in a counterclockwise direction from the entry position to the support position in FIG. 3. The core 72 simultaneously shifts the rod 74 forwardly to effect a corresponding movement of the arm 30.” Col. 4, lines 53-59.

In response to the rejection, Applicants assert that independent claim 32 is unobvious because Holmes and Hasson ‘741 do not overcome the deficiencies of Burbank ‘444. The combination of references neither teaches nor suggests an intravaginal device including “a first mechanism to distally extend at least part of the first pressure applying occluding element from a first position closer to the first operative proximal shaft section to a second position further away from the first operative proximal shaft section.” Claim 32 is also unobvious because the combination neither teaches nor suggests a second occluding member having “a second mechanism to distally extend at least part of the second pressure applying occluding element from a first position closer to the second operative proximal shaft section to a second position further away from the second operative proximal shaft section.”

Claim 33 is unobvious because the cited references do not teach an intravaginal occlusion device including “a fourth mechanism for selectively rotating the second pressure applying occluding element relative to the distal shaft section of the second occluding member, wherein the third and fourth mechanisms operate independently of one another so that the first and second pressure applying occluding elements are pivotable independently of one another.” In one embodiment of the present invention, independent pivoting movement of the first and second pressure applying occluding elements is required for successfully occluding arteries in an environment having asymmetrical uterine artery anatomy. Although Hasson ‘741 teaches pivoting, it does not teach two different mechanisms for independently pivoting first and second pressure applying occluding elements.

Independent claim 34 is unobvious over the cited references because Holmes and Hasson ‘741 do not overcome the deficiencies noted above in Burbank ‘444, namely Burbank ‘444 does not teach an intravaginal device including “a first extending actuator coupled with the first occluding element for selectively moving the first pressure applying surface distally away from the distal end of the first elongated shaft.” Claims 36-37 and 39-40 are unobvious, *inter alia*, by virtue of their dependence from claim 34, which is unobvious for the reasons set forth above.

Claim 38 is unobvious because the references neither teach nor suggest an intravaginal device including “a second rotating actuator coupled with the second occluding element for selectively rotating the second pressure applying surface through a range of angles relative to the second elongated shaft, wherein the first and second rotating actuators operate independently of one another so that the first and second pressure applying surfaces rotate independently of one another.” Claim 38 is also unobvious, *inter alia*, by virtue of its dependence from claim 34, which is unobvious for the reasons set forth above.

Applicants assert that independent claim 41 is unobvious because Burbank ‘444 does not teach an intravaginal device for occluding uterine arteries including “a first extending actuator coupled with the first occluding element for selectively moving the first pressure applying surface between a first position closer to the proximal end of the device and a second position further away from the proximal end of the device” and “a second extending actuator coupled with the second occluding element for selectively moving the second pressure applying surface between a first position closer to the proximal end of the device and a second position further away from the proximal end of the device.”

Independent claim 41 is also unobvious because the references do not teach “a first rotating actuator coupled with the first occluding element for selectively rotating the first pressure applying surface through a range of angles relative to the first elongated shaft” and “a second rotating actuator coupled with the second occluding element for selectively rotating the second pressure applying surface through a range of angles relative to the second elongated shaft.”

Claims 43-45 are unobvious, *inter alia*, by virtue of their dependence from claim 41, which is unobvious for the reasons set forth above.

Claim 46 is unobvious because the combination of references do not teach an intravaginal device “wherein the first and second rotating actuators operate independently of one another so that the first and second pressure applying surfaces are rotatable independently of one another.” Claims 46 is also unobvious, *inter alia*, by virtue of its dependence from claim 41, which is unobvious for the reasons set forth above.

The Examiner rejected claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Hasson ‘680 in view of U.S. Patent No. 6,368,340 to Malecki. The Examiner rejected claims 21 and 22 under 35 U.S.C. § 103(a) as being unpatentable over Hasson ‘680. The Examiner rejected claims 15-18 under 35 U.S.C. § 103(a) as being unpatentable over Hasson ‘680 in view of U.S. Patent No. 6,045,508 to Hossack et al. The above-noted claims are patentable, *inter*

alia, by virtue of their dependence from the patentable claims discussed above.

As it is believed that all of the rejections set forth in the Non-Final Office Action have been overcome, favorable reconsideration and allowance of the present application is earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone Applicants' attorney at (908) 689-8700 in order to overcome any additional objections that she may have.

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